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REMARKSSTATUS SUMMARY

Claims 1-43 are pending in the present Application. Claims 1-43 are rejected by the Examiner. In this Amendment, claims 1, 3, 4, 11-15, 18, 21, 26 and 31-34 have been amended.

Rejections Under 35 U.S.C. § 112

Claims 12-14 and 31-34 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite with regard to the term "pick-up component." In response, Applicant has amended claims 12-14 and 31-34 to replace the term "component" with the term "magnet." In view of the foregoing, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, second paragraph, has been overcome, and therefore respectfully requests that this rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 102Claims 1-5, 7-11, 15, 16 and 18-25 over Shah et al.

Claims 1-5, 7-11, 15, 16 and 18-25 are rejected under 35 U.S.C. § 102(b) as being anticipated by Shah et al. (U.S. Patent No. 3,801,280). Applicant respectfully traverses this rejection for the following reasons.

Applicant has amended claim 1 to clarify that the recited "movable component" includes "a sample carrier holder, and a drivable component attached to the sample carrier holder and actuatable by non-contacting coupling with a driving source." Shah et al. fails to teach a movable component as recited in claim 1.

Referring to Figs. 1 and 2 of Shah et al., Shah et al. teaches a wire basket (2) that may be characterized as a sample carrier holder. The wire basket (2) is suspended in a fixed position within a container (1) and thus is not part of a movable component. Shah et al. emphasizes that this wire basket (2) is not movable. *See* Shah et al., col. 8, lines 11-12 ("unlike testing units wherein the sample holding basket is itself rotated"). In claim 1, as clarified by amendment, the "movable component" includes a "sample carrier holder" and thus the "sample carrier holder" is also movable. Shah et al. also teaches a filter assembly (8) that includes a magnet (16). The

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magnet (16) is coupled to a magnet (46) located outside the container (1) such that the filter assembly (8) is rotatable. The filter assembly (8), however, merely consists of a filter element (12) and liquid conduits (27) and (33) that direct the already-prepared sample out from the container (1). Thus, the filter assembly (8) is not a sample carrier holder within the meaning of claim 1. Therefore, claim 1 does not read on Shah et al.

It is further noted that Shah et al. does not consider the device disclosed therein as being an agitation device. Instead, the filter assembly (8) is gently rotated to prevent clogging. *See Shah et al., col. 7, lines 16-29.*

Claims 2 and 3 depend from claim 1, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 1.

Regarding independent claim 4, Applicant has amended claim 4 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and drivable by non-contacting coupling with a driving source.” Therefore, claim 4 does not read on Shah et al. for reasons similar to those set forth above regarding claim 1.

Claims 5 and 7-10 depend directly or indirectly from independent claim 4, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 4.

Regarding independent claim 11, Applicant has amended claim 11 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and actuatable by non-contacting coupling with a driving source.” Therefore, claim 11 does not read on Shah et al. for reasons similar to those set forth above regarding claim 1.

Regarding independent claim 15, Applicant has amended claim 15 to clarify that the recited “container” includes “a first container section having a first dimension defining a first section volume for containing a drivable component drivable by a driving source, and a second container section having a second dimension different from the first dimension and defining a second section volume different from the first section volume for containing a sample carrier connected to the drivable component.” In the above-identified Office Action, p.4 & 5, the Examiner contends that the “claimed sections do not have any physical limitations.” As amended, however, claim 15 recites first and second container sections that are structurally

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distinct because they have a dimension (e.g., axial length or diameter) that is different. Shah et al. fails to teach this feature. Referring to Figs. 1 and 2 of Shah et al., Shah et al. teaches a wire basket (2) and a filter element (12), each of which is uniformly sized with no physically distinct sections. Therefore, claim 15 does not read on Shah et al.

Claim 16 depends from independent claim 15, and therefore is distinguishable for at least the same reasons as set forth above regarding claim 15.

Regarding independent claim 18, Applicant has amended claim 18 to clarify that the recited "closure device" includes "a body for covering an opening of a container, and a magnet attached to the body for magnetically coupling the closure device with a sample carrier holder." Shah et al. fails to teach this feature. Referring to Figs. 1 and 2 of Shah et al., Shah et al. teaches a filter assembly (12) having a base (9) that includes a magnet (16). Assuming, for the sake of argument only, that the base (9) is a closure device, this base (9) could only be magnetically coupled to a magnet (46) that is employed to rotate the filter assembly (12). This magnet (46) is located outside of the container (1) and is not a "sample carrier holder" as recited in claim 18. Therefore, claim 18 does not read on Shah et al.

Claims 19 and 20 depend directly or indirectly from independent claim 18, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 18.

Regarding independent claim 21, Applicant has amended claim 21 to clarify that the recited "coupling member" is of a "non-contacting" type. Claim 21 is directed to a "support device for supporting a sample carrier." The recited "support device" includes "first and second support members attached to the body and axially spaced for securing a sample carrier between the first and second support members." Shah et al. fails to teach such a "support device."

Applicant's specification defines the term "sample carrier" and provides several examples of devices utilized to support or hold sample carriers. The term "sample carrier" is defined as follows:

As used herein, the term "sample carrier" generally encompasses any dosage form or other structure or material capable of carrying a releasable quantity of material. A "sample carrier" can include any dosage delivery mechanism. In addition to dosage forms, another example of a "sample carrier" is a stent or similar type of prosthesis. . .

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In addition to dosage forms and stents, other non-limiting examples of “sample carriers” include implantable (bio)(chemo)sensors such as glucose sensor, infusion catheters, dental implants, neurostimulation leads, and spinal repair devices, as these terms are understood by persons skilled in the art.

Applicant’s specification, p.6, lines 13-32.

As further examples of devices utilized to support or hold sample carriers, Applicant’s specification at p.1, lines 25-27, describes a “rotating basket (Apparatus 1)” as “a stainless steel basket with mesh sides is provided to contain a tablet, capsule or other dosage form and is rotated by a stainless steel shaft.” Applicant’s specification at p.1, lines 28-29, describes a “reciprocating cylinder (Apparatus 3)” as “a glass reciprocating cylinder with open, mesh-covered ends is provided to contain a dosage form.” Applicant’s specification at p.2, lines 3-6, describes a “reciprocating holder (Apparatus 7)” as “other types of sample holders attached to shafts, such as nylon net bags, CUPROPHAN® material, stainless steel coils, TEFLON® disks, and TEFLON® cylinders, are vertically reciprocated in vessels for the testing of dosage forms such as tablets and transdermal patches.” Applicant’s specification provides additional examples as follows:

As indicated previously, sample carrier 14 can comprise any dosage delivery mechanism—that is, any dosage form or other structure or material capable of carrying a releasable quantity of material such as a drug formulation that can be released from sample carrier 14 when subjected to a solvent or other suitable medium 16. Likewise, the structure of sample carrier support member 64 may depend on the type of sample carrier 14 utilized in sample testing apparatus 10. By way of example only and not as a limitation on the scope of the subject matter disclosed herein, Figures 1 and 2 illustrate a sample carrier 14 provided in the form of a stent. Accordingly, sample carrier support member 64 in this example is structured to serve as a stent holder. In other embodiments, sample carrier support member 64 can comprise a basket, disk, netting, cell, cylinder, or the like as needed for supporting or containing other types of sample carriers 14 (e.g., tablets, transdermal patches, etc.) during reciprocation through media 16.

Applicant’s specification, p.9, lines 19-30.

Referring to Figs. 1 and 2 of Shah et al., Shah et al. teaches a wire basket (2) that may be characterized as a support device for supporting a sample carrier. The wire basket (2), however, does not include “a coupling member attached to the body for non-contacting coupling with a driving source.” Instead, the wire basket (2) is suspended in a fixed position within a container

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(1) by being mechanically coupled to a rod (3) that is in turn mechanically coupled to a lid (4). Shah et al. also teaches a filter assembly (8) that includes a magnet (16). The filter assembly (8), however, merely consists of a filter element (12) and grooves or channels (27) and (33) that assist in directing liquid out from the container (1) for analysis. Thus, within the meaning of claim 21, the filter assembly (8) of Shah et al. does not support a structure or composition that includes a releasable quantity of material, nor does the filter assembly (8) support a device that would be implanted for an in vivo function such as, for example, a sensor, a neurostimulation lead, etc. Therefore, claim 21 does not read on Shah et al.

Claims 22-25 depend directly or indirectly from independent claim 21, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 21.

In view of the foregoing, Applicant respectfully submits that claims 1-5, 7-11, 15, 16 and 18-25 are patentable under 35 U.S.C. § 102(b) over Shah et al. Therefore, Applicant respectfully requests that this rejection be withdrawn.

Claims 1-11, 15-17, 21-30 and 35-43 over Zuellig et al.

Claims 1-11, 15-17, 21-30 and 35-43 are rejected under 35 U.S.C. § 102(b) as being anticipated by Zuellig et al. (U.S. Patent No. 6,126,904). Applicant respectfully traverses this rejection for the following reasons.

Applicant has amended claim 1 to clarify that the recited "movable component" includes "a sample carrier holder, and a drivable component attached to the sample carrier holder and actuatable by non-contacting coupling with a driving source." Zuellig et al. fails to teach a movable component as recited in claim 1.

Referring to Fig. 1B of Zuellig et al., Zuellig et al. teaches a magnet (35) located in a reaction vessel (30) that is actuated by a magnet (500) located outside the reaction vessel (30). The magnet (35) is similar to any other conventional magnetic agitating element, such as a magnetic stir bar or bead, and is not a "sample carrier holder" within the meaning of claim 21. Zuellig et al. also teaches a frit (32) that is fixed in position within the reaction vessel (30). As noted by the Examiner, Zuellig et al. teaches that the reaction vessel (30) is employed to carry out synthetic reactions involving starting materials that are supported on a solid support. See Zuellig et al., col. 5, lines 16-32. However, it is the frit (32) that supports the solid support and

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accompanying starting materials, and not the magnet (35). *See* Zuellig et al., col. 7, lines 46-53. Thus, even accepting—for the sake of argument only—the Examiner’s contention that “the solid support elements [of Zuellig et al. meet] the limitation of a sample carrier that releases compounds” (above-identified Office Action, p.3), these “solid support elements” are not part of a “movable component” as recited in claim 1. Therefore, claim 1 does not read on Zuellig et al.

Claims 2 and 3 depend from claim 1, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 1.

Regarding independent claim 4, Applicant has amended claim 4 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and drivable by non-contacting coupling with a driving source.” Therefore, claim 4 does not read on Zuellig et al. for reasons similar to those set forth above regarding claim 1.

Claims 5-10 depend directly or indirectly from independent claim 4, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 4.

Regarding independent claim 11, Applicant has amended claim 11 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and actuatable by non-contacting coupling with a driving source.” Therefore, claim 11 does not read on Zuellig et al. for reasons similar to those set forth above regarding claim 1.

Regarding independent claim 15, Applicant has amended claim 15 to clarify that the recited “container” includes “a first container section having a first dimension defining a first section volume for containing a drivable component drivable by a driving source, and a second container section having a second dimension different from the first dimension and defining a second section volume different from the first section volume for containing a sample carrier connected to the drivable component.” In the above-identified Office Action, p.4 & 5, the Examiner contends that the “claimed sections do not have any physical limitations.” As amended, however, claim 15 recites first and second container sections that are structurally distinct because they have a dimension (e.g., axial length or diameter) that is different. Zuellig et al. fails to teach this feature. Referring to Fig. 1B of Zuellig et al., Zuellig et al. teaches a

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reaction vessel (30) that is uniformly sized with no physically distinct sections. Therefore, claim 15 does not read on Zuellig et al.

Claims 16 and 17 depend from independent claim 15, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 15.

Regarding independent claim 21, Applicant has amended claim 21 to clarify that the recited "coupling member" is of a "non-contacting" type. Claim 21 is directed to a "support device for supporting a sample carrier." The recited "support device" includes "first and second support members attached to the body and axially spaced for securing a sample carrier between the first and second support members." Zuellig et al. fails to teach such a "support device."

Applicant's specification defines the term "sample carrier" and provides several examples of devices utilized to support or hold sample carriers, as discussed above in conjunction with the rejection of claim 21 based on Shah et al.

As discussed above, Zuellig et al. teaches a magnet (35) located in a reaction vessel (30) that is actuated by a magnet (500) located outside the reaction vessel (30). The magnet (35) is not a "support device" within the meaning of claim 21. Zuellig et al. also teaches a frit (32) that is fixed in position within the reaction vessel (30). The frit (32) is employed to support the solid support and accompanying starting materials. See Zuellig et al., col. 7, lines 46-53. Assuming, for the sake of argument only, that the frit (32) may be characterized as a support device within the meaning of claim 21, the frit (32) still does not include a "coupling member" as recited in claim 21. Therefore, claim 21 does not read on Zuellig et al.

Claims 22-25 depend directly or indirectly from independent claim 21, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 21.

Regarding claim 26, Applicant has amended claim 26 to delete language that is similarly recited in dependent claim 35. Independent claim 26 recites "providing a movable component in a container, the movable component supporting a sample carrier." Zuellig et al. fails to teach this aspect or feature. As discussed above, Zuellig et al. teaches a magnet (35) located in a reaction vessel (30) that is actuated by a magnet (500) located outside the reaction vessel (30). The magnet (35) is similar to any other conventional magnetic agitating element, such as a magnetic stir bar or bead, and does not support a sample carrier. Zuellig et al. also teaches a frit (32) that is fixed in position within the reaction vessel (30), and thus is not a "movable component." Even

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assuming—for the sake of argument only—that the frit (32) or the material, supported thereon constitute a “sample carrier,” none of these elements is not supported by a “movable component” as recited in claim 26. Therefore, claim 26 does not read on Zuellig et al.

Claims 27-30 and 35 depend directly or indirectly from independent claim 26, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 26.

Independent claim 36 recites “providing a closure member for sealing an open end of a container,” and “coupling the closure member with a support device supporting a sample carrier.” Zuellig et al. fails to teach this aspect or feature. As discussed above, Zuellig et al. teaches a magnet (35) located in a reaction vessel (30) that is actuated by a magnet (500) located outside the reaction vessel (30). The magnet (35) is neither a “closure member” nor a “support device supporting a sample carrier” within the meaning of claim 36. Zuellig et al. also teaches a frit (32) that is fixed in position within the reaction vessel (30). The frit (32) is not a “closure member.” Moreover, even assuming—for the sake of argument only—that the frit (32) is a support device, the frit (32) is not coupled to a closure member.

Additionally, referring to 4-7A of Zuellig et al., Zuellig et al. teaches a common manifold (110) containing bosses (144) fitting into the respective open tops of reaction vessels (30), and a valve manifold (114) containing valve bosses (200) fitting into the respective open bottoms of the reaction vessels (30). Even assuming, for the sake of argument only, that these bosses (144) and (200) constitute “closure members,” none of these bosses (144) and (200) are coupled with a “support device supporting a sample carrier” as recited in claim 36. Therefore, claim 36 does not read on Zuellig et al.

Claims 37-43 depend directly or indirectly from independent claim 36, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 36.

In view of the foregoing, Applicant respectfully submits that claims 1-11, 15-17, 21-30 and 35-43 are patentable under 35 U.S.C. § 102(b) over Zuellig et al. Therefore, Applicant respectfully requests that this rejection be withdrawn.

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Claims 1-4, 7-11, 15, 16 and 18-20 over Nielsen

Claims 1-4, 7-11, 15, 16 and 18-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nielsen (U.S. Patent No. 6,582,116). Applicant respectfully traverses this rejection for the following reasons.

Applicant has amended claim 1 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and actuatable by non-contacting coupling with a driving source.” Nielsen fails to teach a movable component as recited in claim 1.

Referring to Fig. 1 of Nielsen, Nielsen teaches a mixing apparatus (1) that includes a conventional paddle-type stirrer—namely, an impeller (3) consisting of a blade (27) attached to a shaft (25)—that extends into a vessel (5). Referring to Fig. 8 of Nielsen, Nielsen teaches that the impeller (351) may be actuated by a magnetic coupling (353). Nielsen fails to teach any form of a sample carrier holder, particularly one that would be part of a “movable component” as recited in claim 1. Applicant further notes that the language of claim 1 clearly distinguishes between a “container” on the one hand and, on the other hand, a “movable component” that would reside in such a container.

Claims 2 and 3 depend from claim 1, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 1.

Regarding independent claim 4, Applicant has amended claim 4 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and drivable by non-contacting coupling with a driving source.” Therefore, claim 4 does not read on Nielsen for reasons similar to those set forth above regarding claim 1.

Claims 7-10 depend directly or indirectly from independent claim 4, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 4.

Regarding independent claim 11, Applicant has amended claim 11 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and actuatable by non-contacting coupling with a driving source.” Therefore, claim 11 does not read on Nielsen for reasons similar to those set forth above regarding claim 1.

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Regarding independent claim 15, Applicant has amended claim 15 to clarify that the recited "container" includes "a first container section having a first dimension defining a first section volume for containing a drivable component drivable by a driving source, and a second container section having a second dimension different from the first dimension and defining a second section volume different from the first section volume for containing a sample carrier connected to the drivable component." In the above-identified Office Action, p.4 & 5, the Examiner contends that the "claimed sections do not have any physical limitations. As amended, however, claim 15 recites first and second container sections that are structurally distinct because they have a dimension (e.g., axial length or diameter) that is different. Nielsen fails to teach this feature. Referring to Figs. 1 and 8 of Nielsen, Nielsen teaches a vessel (5) or (313) that is uniformly sized with no physically distinct sections. Therefore, claim 15 does not read on Nielsen.

Claim 16 depends from independent claim 15, and therefore is distinguishable for at least the same reasons as set forth above regarding claim 15.

Regarding independent claim 18, Applicant has amended claim 18 to clarify that the recited "closure device" includes "a body for covering an opening of a container, and a magnet attached to the body for magnetically coupling the closure device with a sample carrier holder." Nielsen fails to teach this feature. Referring to Fig. 8 of Nielsen, Nielsen teaches an impeller (351) located in a vessel (313) that is driven by a magnetic coupling (353) located outside of the vessel (313). The magnetic coupling (353) can only be coupled to the shaft that extends through a header plate (335) in Fig. 8. Nielsen fails to teach any form of a "sample carrier holder" to which any magnet could be coupled. Therefore, claim 18 does not read on Nielsen.

Claims 19 and 20 depend directly or indirectly from independent claim 18, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 18.

In view of the foregoing, Applicant respectfully submits that claims 1-4, 7-11, 15, 16 and 18-20 are patentable under 35 U.S.C. § 102(b) over Nielsen. Therefore, Applicant respectfully requests that this rejection be withdrawn.

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Claims 1-4, 7-11, 15 and 16 over Jahn et al.

Claims 1-4, 7-11, 15 and 16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Jahn et al. (U.S. Patent No. 7,074,364). Applicant respectfully traverses this rejection for the following reasons.

Applicant has amended claim 1 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and actuatable by non-contacting coupling with a driving source.” Jahn et al. fails to teach a movable component as recited in claim 1.

Referring to Fig. 1 of Jahn et al., Jahn et al. teaches a sample vessel (12) in which a conventional magnetically-driven paddle-type stirrer (4) extends. Similar to Nielsen discussed above, Jahn et al. fails to teach any form of a sample carrier holder, particularly one that would be part of a “movable component” as recited in claim 1. Applicant further notes that the language of claim 1 clearly distinguishes between a “container” on the one hand and, on the other hand, a “movable component” that would reside in such a container.

Claims 2 and 3 depend from claim 1, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 1.

Regarding independent claim 4, Applicant has amended claim 4 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and drivable by non-contacting coupling with a driving source.” Therefore, claim 4 does not read on Jahn et al. for reasons similar to those set forth above regarding claim 1.

Claims 7-10 depend directly or indirectly from independent claim 4, and therefore are distinguishable for at least the same reasons as set forth above regarding claim 4.

Regarding independent claim 11, Applicant has amended claim 11 to clarify that the recited “movable component” includes “a sample carrier holder, and a drivable component attached to the sample carrier holder and actuatable by non-contacting coupling with a driving source.” Therefore, claim 11 does not read on Jahn et al. for reasons similar to those set forth above regarding claim 1.

Regarding independent claim 15, Applicant has amended claim 15 to clarify that the recited “container” includes “a first container section having a first dimension defining a first

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section volume for containing a drivable component drivable by a driving source, and a second container section having a second dimension different from the first dimension and defining a second section volume different from the first section volume for containing a sample carrier connected to the drivable component.” In the above-identified Office Action, p.4 & 5, the Examiner contends that the “claimed sections do not have any physical limitations. As amended, however, claim 15 recites first and second container sections that are structurally distinct because they have a dimension (e.g., axial length or diameter) that is different. Jahn et al. fails to teach this feature. Referring to Fig. 1 of Jahn et al., Jahn et al. teaches a sample vessel (12) that is uniformly sized with no physically distinct sections. Therefore, claim 15 does not read on Jahn et al.

Claim 16 depends from independent claim 15, and therefore is distinguishable for at least the same reasons as set forth above regarding claim 15.

In view of the foregoing, Applicant respectfully submits that claims 1-4, 7-11, 15 and 16 are patentable under 35 U.S.C. § 102(b) over Jahn et al. Therefore, Applicant respectfully requests that this rejection be withdrawn.

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CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters.

Respectfully submitted,

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